Overview of Presentation

• What does “effectiveness” look like?

• How do you assess effectiveness in your organization?

• What is the government looking for from you to show effectiveness?

Measuring Compliance Program Effectiveness

Structure, Process and Outcome Indicators

1. **Structure Indicators** – foundational elements, e.g., policies, procedures, committees, reporting structure, hotline

2. **Process Indicators** – achievement of individual objectives, e.g., survey completed, LEIE screening being done, education plan developed and implemented

3. **Outcome Indicators** – more behavioral - the **impact** that compliance efforts have on an organization’s level of compliance
Baseline Questions

- How compliance program is structured
- Who is responsible
- Compliance reporting system
- Goals and limitations of compliance program
- Significant risks addressed
- Level and adequacy of compliance resources

Operational Questions

- Code of Conduct
- Policies and procedures addressing compliance risks and establishing internal controls
- Compliance infrastructure
- Compliance Officer autonomy and authority
- Measures to prevent violations
- Board communication and involvement

Analyzing Effectiveness

- Organization
  - Culture
- Governance and Senior Management
  - Commitment
- Structure and Processes
  - Internal Controls
- Assessment and Enhancement
  - Auditing and Monitoring
Organizational Structure

• Values and rewards:
  – Compliance
  – Prevention
  – Detection
  – Resolution

• Code of Ethics/Conduct

• Core Values

• Compliance as part of annual performance review

Governance and Senior Management

• Emphasized by OIG
  – Supplemental Compliance Guidance for Hospitals
  – Board Educational Resource

• How measured?
  – Formal commitment to compliance
  – Active involvement
  – Allocation of resources
  – Empowerment of compliance professionals

Governance and Senior Management: Documented Effectiveness

• Demonstrate and document efforts to get it right the first time by:
  – Evaluation of new business ventures for potential risk
  – Proper delegation of authority and accountability
  – Timely response to newly developed rules and regulations
  – Systematic testing of internal control systems that are tested
Senior Management Responsibilities: Creating a Culture of Compliance

- Goal is to create an environment or culture which:
  - Encourages open discussion of errors and concerns raised by employees
  - Allows for prompt reporting of compliance concerns or potential misconduct
  - Designs systems and processes that:
    • Ensure compliance
    • Contain adequate controls (compliance, quality and safety)
    • Are supported by detailed policies and procedures

Compliance Committee Responsibilities: Governance and Oversight

- Ensure that appropriate policies and procedures are in place to preserve and safeguard the organization's assets
- Ensure proper ethical and legal standards are present and maintained in meeting all applicable laws, rules and regulations
- Monitor compliance with applicable laws, rules and regulations

Audit/Compliance Committee Responsibilities:

- Compliance Audit Plan
  • Does your entity have an annual audit and/or compliance audit plan?
  • Does it address billing systems and claims accuracy?
  • Does it identify causes of non compliance?
  • Do you utilize qualified auditors with expertise in the risk areas?
  • Does it include unannounced audits?
  • What is your protocol for following up on identified issues and developing corrective action plans?
Audit Emphasis: Specific Risk Areas

- OIG Work plan
- OIG Semi-Annual Report
- CMS Comprehensive Error Rate Testing (CERT) report
- CMS findings from Recovery Audit Contractors (RACs)
- OIG Compliance Program Guidance
- OIG Corporate Integrity Agreements for similar entities
- CMS or OIG fraud alerts
- CMS local medical review policies or national coverage decisions
- Program requirements
- Specific risk areas identified for provider’s industry segment

Audit Findings: How to Respond to Potential Non-Compliance

- Document responses to issues
- Investigate as appropriate
  - Internal and external resources may be appropriate depending on situation
- Develop corrective actions plans and ensure they are implemented and tracked as appropriate
- Refund all identified overpayments

Corrective Actions: Enforcement of Disciplinary Standards

- Standards well-publicized
- Consistently enforced
- Exclusion lists checked
- Emphasis on non-retaliation
Compliance Plan Review:
Frequency of Effectiveness Reviews

• Annual review of compliance plan, including compliance with seven elements, is essential. Develop baseline and use that as benchmark to track progress. Include the following issues for review:
  ➢ Billing and coding error rates
  ➢ Refunds: both voluntary and involuntary
  ➢ Employee awareness of compliance program
  ➢ Hotline calls and other referrals
  ➢ Number of investigations and outcomes
  ➢ Responses to issues and follow up on corrective action plans
  ➢ Consistent enforcement and discipline

Compliance Program Review

1. Designation of Compliance Officer & Compliance Committee

Key Questions:
• Is there a compliance officer who is well qualified, a member of senior management, and who is supported by the Compliance Committee and Board?
• Is there a clear mission and plan for the compliance office?
• Are there sufficient resources available?
• Is there an appropriate relationship between the compliance officer and general counsel?

1. Designation of Compliance Officer & Compliance Committee

Key Questions:
• Is there an active compliance committee?
• Is the committee comprised of trained representatives of each relevant functional department and members of senior management?
• Are ad hoc groups or task forces utilized?
Compliance Program Review

Key Questions

1. Does the compliance officer have access to:
   - Board of Directors or Governing Body
   - Senior Management
   - Legal Counsel

2. Does the compliance officer have good internal working relationships?

3. Does the compliance officer make regular reports to senior management and the Board?

Compliance Program Review

2. Development of Compliance Policies and Procedures and Standard of Conduct

• Have standards of conduct and policies/procedures been distributed to:
  - Governing body and/or Board?
  - All officers?
  - All managers?
  - Employees?
  - Contractors?
  - Medical Staff?

Compliance Program Review

2. Development of Compliance Policies and Procedures and Standard of Conduct

• Are policies and procedures:
  - Clearly written?
  - Relevant to day to day responsibilities?
  - Readily available to those who need them?
  - Re-evaluated on a regular basis (at least annually)
  - Is compliance with policies and procedures monitored?
Compliance Program Review

2. Development of Compliance Policies and Procedures and Standard of Conduct

- Does the entity have risk assessment tools that evaluate:
  - Federal health care program requirements?
  - OIG compliance program guidances (if relevant)
  - OIG work plan and other internal work plans?
  - Special Advisory Bulletins from CMS and OIG
  - OIG and CMS Special Fraud Alerts?

Compliance Program Review

3. Developing Open Lines of Communication

- Has the entity fostered an organizational culture that:
  - Encourages open communication?
  - Prevents retaliation?
  - Publicizes how and when to report instances of misconduct?
- Does the entity have a hotline? If so:
  - How long has it been established and, if not, why has one not been?
  - Is the hotline publicized?
  - Are calls logged and tracked for trends?
  - Do callers receive feedback?

Compliance Program Review

- Are all potential fraud and abuse issues investigated?
- Are results of internal investigations routinely reported to senior management and the governing body?
- Is the governing body actively engaged in pursuing appropriate remedies to institutional or recurring problems?
- How are:
  - Compliance program activities communicated within the organization?
  - How frequently are they communicated?
Compliance Program Review

4. Assessing Training and Education

- Does the entity have qualified trainers?
- Do the trainers:
  - Conduct annual compliance training for all staff?
  - Is there general and specific training?
- Is the training evaluated for effectiveness? If so, how often?
- Has the entity:
  - Kept current on changes in Federal health care program requirements?
  - Adapted training and education accordingly?
  - Example: recent Stark self-disclosure protocol issued by CMS or new fraud and abuse regs dealing with provider enrollment issued by CMS

- Is education and training developed considering the following factors?
  - Results of audits and investigations
  - Results of previous training and education activities
  - Hotline reports received or complaints received
  - OIG/CMS communications and guidances
- Has entity evaluated the effectiveness of training and education utilizing appropriate methods?
- Has the governing body been provided with appropriate training?
- Are training and education activities well documented?
- Are there attendance requirements? How are those tracked?

Compliance Program Review

4. Assessing Training and Education

- Is education and training developed considering the following factors?
  - Results of audits and investigations
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- Has the governing body been provided with appropriate training?
- Are training and education activities well documented?
- Are there attendance requirements? How are those tracked?

Compliance Program Review

5. Internal Monitoring and Auditing

- Has the entity evaluated error rates based on annual audit results?
- Is there an ongoing effort to uncover hidden weaknesses and deficiencies?
- Do audits include a review of clinical documentation?
- Does the hospital have in place a process for promptly responding to detected deficiencies?
- Are all deficiencies promptly and thoroughly investigated?
- Are corrective action plans developed and verified after implemented?
- When identified, are overpayments promptly repaid and disclosed?
### Compliance Program Review

#### 5. Internal Monitoring and Auditing

- Is an annual audit plan developed?
- Does the audit plan include?
  - Assessment of billing systems?
  - Claims accuracy?
  - Root cause analysis of errors?
- Is audit staff qualified and appropriately certified?
- Are resources available for unscheduled reviews as requested by the compliance officer?

#### 6. Response to Detected Deficiencies

- Does the hospital have in place a process for promptly responding to detected deficiencies?
- Are all deficiencies promptly and thoroughly investigated?
- Are corrective action plans developed?
- Is corrective action taken verified after implemented?
- When identified, are overpayments promptly repaid and disclosed?

#### 7. Enforcement of Disciplinary Standards

- Are disciplinary standards well publicized?
- Are disciplinary standards consistently enforced and documented?
- Are employees, contractors, and medical staff checked routinely against the OIG and GSA sanction lists? Other lists such as DHS or INS?
The “Five” Questions

1) Does your organization have a compliance officer?
2) Do you know who the compliance officer is?
3) Do you know how to contact the compliance officer?
4) Are you obligated by your organization to report improper or unethical conduct?
5) Can you provide an example of improper conduct that you would be required to report?

Outcomes: Achieving Results

- Employee awareness and understanding of compliance program
- Employee awareness and understanding of laws, regulations and policy requirements
- Improving culture and better cohesiveness in oversight activities
- Decrease in incidents of non-compliance
- Reduction of fines and penalties

Measuring Compliance Program Effectiveness

Different Tools to Measuring Effectiveness

1. FSG 7 elements of an effective compliance program
2. OIG Model Guidances, e.g. Managed Care, Hospital, DME, SNF, etc.
3. Industry benchmarks – national/regional
4. Your organization - comparison between performance from year to year
5. Related outcomes, e.g., repayment costs for inaccurate billing/coding
What is the Government Focus

Effective used 24 times (14 times “effective compliance program”) in OIG guidance

Desired Effect: “promote adherence to applicable Federal and State law, and the program requirements of Federal, State and private health plans.”

How can we anticipate what the government will measure if our compliance program is under review?

- Federal Sentencing Guidelines are the basis of the assessment
- What determines “effectiveness”?
- Are there specific resources on what it is we need to demonstrate?
- Resource: Corporate Integrity Agreements/Settlement Letters

CMS Compliance Effectiveness Pilot

Lessons Learned:

- Importance of Compliance Officer
- Communication essential to effectiveness of Audits
- Training should be tailored to individuals and issues at hand
- Policies and Procedures should be clear and concise
- Changes made to training and auditing had a huge impact on accuracy of claims submission
- Essential to have a “culture” of compliance

OIG Settlement Letter

Key Elements Reviewed

- Code of conduct and standards of conduct
- Budget of compliance department
- Policies and procedures related to federal health care program billing, coding and fraud and abuse laws
- Policies and procedures controlling discipline
- Description of process used to identify excluded/convicted individuals
- Training programs – contents, frequency, attendance
- Internal reporting mechanism:
  - Methods for making workforce aware
  - Procedures used to track calls
  - Summaries of reports
DOJ’s Effectiveness Determination Factors

- Comprehensiveness of the compliance program
- Extent and pervasiveness of the misconduct
- Number and level of employees involved in the misconduct
- Seriousness, duration and frequency of the misconduct
- Remedial actions taken by the entity (e.g., disciplinary action against violators discovered by existing compliance program)
- Promptness of self-disclosure

Ref: USAM 9-28.000 - Principles Of Federal Prosecution Of Business Organizations

DOJ’s Effectiveness Determination Factors

- Mechanisms for informing board of misconduct
- Whether board exercised independent judgment on issue
- Independence and sufficiency of internal audit mechanisms
- Paper program only or actively operating and being revised as necessary
- Sufficient resources for staffing to audit, document, analyze and utilize results of compliance efforts
- Are employees informed about the program and convinced of the entity’s commitment

Ref: USAM 9-28.000 - Principles Of Federal Prosecution Of Business Organizations

Summary

Measuring CP Effectiveness Provides:

1. Compliance Program
   - Valuable insight to move the program from one level to next
     - Focus limited resources on high profile/risk areas

2. Organization
   - Quantifies “value” of program within the entity and demonstrates commitment of leadership to continually improve oversight activities

3. Regulators/Payors
   - Documents “good faith” efforts by organization to government
Mandatory Compliance

- Affordable Care Act specified that compliance programs will become mandatory as a condition of participation in Medicare once CMS/OIG promulgate regulations stating what is an “effective” compliance program.

MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM

1. Do you have written policies and procedures (Ps & Ps) and/or Standards of Conduct that:
   - Articulate the organization's commitment to comply with all applicable Federal and State standards?
   - Describe compliance expectations as embodied in the standards of conduct?
   - Implement the operation of the compliance program?
   - Provide guidance to employees and others on dealing with potential compliance issues?
   - Identify how to communicate compliance issues to appropriate compliance personnel?
   - Describe how potential compliance issues are investigated and resolved by the organization?
   - Include a policy of non-intimidation and no-retaliation for good faith participation in the compliance program; including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials?

2. Are your Ps & Ps detailed and specific in their description of the operation of the compliance program?

3. Do you distribute your Standards of Conduct and Ps & Ps to your employees within 90 days of hire, when there are updates and annually thereafter?

4. Do you update your Ps & Ps to incorporate changes in applicable laws, regulations and other program requirements?

5. Does your CEO receive your compliance officer’s reports on the status and activities of the compliance program?
MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM

6. If your compliance officer does not report directly, in-person to your CEO, are his/her reports routed through the President of the division that houses the Medicare and/or through the President of the organization rather than through operational management?

7. Does your compliance officer have express authority (oral or written, preferably written) to make in-person reports to your CEO and Board of Directors in the compliance officer’s sole discretion?

8. Is your compliance officer employed by your organization, parent organization, or corporate affiliate?

9. If employed by your parent or corporate affiliate, does your compliance officer have detailed involvement in and familiarity with your Medicare operational and compliance activities?

Questions?